1	2	3	4	5	6	7	8
J & K	24	20	17	24	2	0	6
Jharkhand	41	21	17	46	2	2	26
Karnataka	76	64	31	561	27	28	40
Kerala	23	45	18	103	5	6	47
Lakshadweep	3	1	1	0	0	0	0
Madhya Pradesh	54	59	49	103	3	2	66
Maharashtra	114	96	43	604	37	28	42
Manipur	24	3	10	54	6	6	57
Meghalaya	10	5	7	11	1	0	6
Mizoram	17	8	7	20	1	2	42
Mumbai (MC)	0	0	23	0	0	0	36
Nagaland	29	8	11	65	4	4	38
Orissa	54	56	19	129	3	4	44
Pondicherry	10	5	4	10	1	1	0
Punjab	32	51	17	57	3	3	24
Rajasthan	46	43	47	178	4	4	46
Sikkim	7	2	5	13	1	0	8
Tamil Nadu	109	94	95	783	27	35	35
Tripura	10	6	5	4	1	2	16
Uttar Pradesh	98	68	79	205	7	5	93
Uttarakhand	16	13	9	39	1	0	4
West Bengal	55	62	44	141	4	8	63

Protection of participants of clinical trials

68. SHRI MAHENDRA MOHAN:
SHRIMATI SHOBHANA BHARTIA:
SHRIMATI MOHSINA KIDWAI:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Indian Council of Medical Research (ICMR) has recently drafted guidelines for compensation to participants for research related injury in the country;

(b) if so, the details thereof;

(c) whether AIIMS has been doing clinical trials using stem cells as well and propose to start a new batch of trials for the patients of Parkinsons disease shortly; and

(d) if so, how Government is going to protect the participants of clinical trials?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) and (b) The Indian Council of Medical Research (ICMR), Forum for

Ethical Review Committees in India (FERCI), and Indian Society of Clinical Research (ISCR) have issued draft Guidelines for Compensation to participants for Research Related Injury in India for comments. These guidelines are available on ICMR website *www.icmr.nic.in.* However, excerpts from the guidelines are given in the Statement (*See* below).

(c) AIIMS is doing clinical trial using Autplogous Bone in India.

(d) As per schedule Y of Drugs and Cosmetics Act (Amended 2005) the Institutional Ethics Committee is responsible for protecting the rights, safety, well being of all trials subjects. As per Guidelines for Stem Cell Research and Therapy issued by Department of Biotechnology & Indian Council of Medical Research (2007), all clinical trials with any stem cells shall have prior approval by Institutional Committee for Stem Cell Research & Therapy (ICSCRT), Institutional Ethics Committee (IEC) and Drug Controller General of India (DCGI) for marketable product.

Statement

Details of the guidelines recently drafted by ICMR

- **Scope of Guidelines**

- These Guidelines apply to all clinical research whether sponsored by the Pharmaceutical or Medical Device Industry, Government or Academia or individual investigators.
- These guidelines do not apply to Post Marketing Surveillance and ancillary care.

- **Basic Principles**

- Compensation be provided to the research participants when temporary or permanent injury occurs due to participation in the clinical research.
- Compensation be paid to a child injured in-utero through the participation of the parent in clinical research.
- Compensation be paid when injury is caused by a procedure which has been undertaken to manage an adverse reaction occurring during the research.
- Compensation be paid irrespective of
  - whether injury was foreseeable/predictable or not.
  - The fact that the research participant had freely consented in writing to participate in the research.
  - The fact that the injury was caused by the comparator product(s) under investigation in the clinical research.

- Compensation be paid irrespective of the fact that the injury was caused through a departure from the agreed protocol, scientific misconduct or negligence by the Investigator.
- Compensation may be excluded in light of factors described in Section 5.4.
- All research related injuries be compensated irrespective of their causes and individuals/agencies responsible.